

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Forbes Jones et al.	:	
	:	COBALT-NICKEL-CHROMIUM-
Group Art Unit 1742	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF TITANIUM
Serial No. 10/656,918	:	NITRIDE INCLUSIONS
	:	
Filed September 5, 2003	:	
	:	Confirmation No. 8375
Examiner Jessee Roe	:	

DECLARATION OF ROBERT J. MYERS

Pittsburgh, Pennsylvania 15222-2312

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Robert J. Myers, declare as follows:
2. I am a citizen of the United States and currently reside at 7435 Inverness Commons, Fort Wayne, Indiana.
3. I am over the age of eighteen and am competent to make the statements in this Declaration.
4. I am named as an inventor on the above-identified U.S. patent application ("the Application"), and I am thoroughly familiar with the Application and the claims currently pending in the Application. I also am thoroughly familiar with the alloy described in the Application and with the surgical implant products made from the alloy.

5. I currently hold the position of Executive Vice President of Fort Wayne Metals Products Research Corporation ("FWM"), Fort Wayne, Indiana, where I began working in 1998. I am responsible for business development and all commercial activity within FWM. As such, I am thoroughly familiar with the production, marketing, and sales of all FWM's products. Prior to joining FWM, I was employed at ATI Allvac, a business of Allegheny Technologies Incorporated, where I was a Product Manager responsible for the company's marketing activity associated with Allvac's entry into rod and coil specialty metals and titanium alloys. Prior to my employment at Allvac, I held various financial and marketing positions with Haynes International, a world leader in the market for cobalt and nickel base alloys. I have been an active member of the International Organization on Shape Memory and Superelastic Technologies (SMST), ASM International, and the Indiana Medical Device Manufacturers Council.

6. Since 2003, FWM has purchased rods and coils of a particular cobalt-nickel-chromium-molybdenum alloy from ATI Allvac having a chemistry and microstructure that falls squarely within at least Claim 1 of the Application. Specifically, the ATI Allvac alloy has the chemistry and microstructure recited in the current form of the Application's Claim 1. FWM processes the ATI Allvac alloy into small diameter wire of several diameters, and markets and sells the small diameter wire as 35N LT[®] wire for use in surgical implant products. Medical device companies purchase FWM's 35N LT wire for use in a number of surgical implant applications, including cardiac pacemaker and defibrillator leads and stylets, catheters, orthopedic cables, and stents.

7. From the time FWM began selling 35N LT wire I have been responsible for all marketing and sales of the product. As such, I am thoroughly familiar with the quantities of 35N LT wire FWM has sold and the gross revenues for such sales, and I routinely interact with FWM's customers for the product and request and obtain comments from those customers about their experiences using the product.

8. FWM has enjoyed incredible success selling 35N LT wire for use in surgical implant applications. FWM has generated more than \$6M in gross revenues from sales of 35N LT wire since it began selling the product in mid-2003. The following chart lists the number of discrete orders, the total weight, and the total length in linear

feet of 35N LT wire that FWM has sold to manufacturers of surgical implant devices in the years 2003-2006. Figure 1 graphically depicts the number of discrete orders (each order is assigned a distinct "part number") that FWM filled for 35N LT wire in each of years 2003-2006. Figure 2 graphically depicts the total linear feet of 35N LT wire FWM shipped in each of years 2003-2006.

Year	2003	2004	2005	2006
Number of Parts	22	99	130	253
Number of Invoices	23	140	270	483
Linear Feet (thousand feet)	357	19,273	55,190	107,323

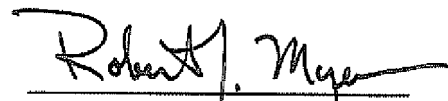
9. The figures in the above table and in the attached figures tell a compelling story of the very substantial market demand that has developed for 35N LT wire since its introduction. FWM filled its first commercial order for 35N LT wire in June of 2003. In the entire second half 2003, FWM filled 15 orders for a total of about 357,000 linear feet of 35N LT wire. In 2004, the number of filled orders quadrupled and, as is evident from the fact that FWM shipped over 19 million feet of wire that year, the average order in 2004 was substantially larger than in the prior year. In 2005, market demand for the wire accelerated – the number of discrete orders increased to 170% of the prior year's level and the total length of wire shipped, just over 55 million linear feet, was about 280% of the 2004 figure. Sales continued to grow in 2006 – orders increased to 150% of the prior year's number and total linear feet shipped advanced to 190% of the prior year's total. Therefore, per-year increases in product sales have been very significant, and this trend is continuing so far through 2007. The tremendous commercial success of 35N LT wire is perhaps better shown by the increase in the three-year period from 2004-2006. In 2006 the number of orders shipped was over 260%, and the total linear feet shipped was over 550% of the 2003 figures. I believe that this sales data convincingly shows that FWM's 35N LT small diameter wire product has proven to be a tremendous commercial success.

10. A number of different commercially available alloys are suitable for use in surgical implant applications such as in cardiac pacemaker and defibrillator leads and orthopedic cables, and stents. Although medical device manufacturers choose from among these alloys for these surgical implant applications based on a number of factors, chief among them is the fatigue resistance of the alloy (for example, fracture due to fatigue is the primary failure mechanism for cardiac pacemaker leads). Given the understandable importance of resistance to fatigue-induced fracture in surgical implant applications, application in which the product will be implanted in the body and cannot be retrieved and replaced without surgery, alloy cost is not of primary importance to surgical implant device manufacturers. In these applications, manufacturers seek out and purchase otherwise suitable (biocompatible) alloys having the best fatigue resistance properties since doing so will reduce the possibility of device failure.

11. The substantial commercial success that FWM has had with 35N LT wire is directly attributable to its substantially improved fatigue resistance relative to other alloys suitable for use in surgical implant applications. As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications. I do not base this conclusion only on the substantial, rapid, and continuing increase in FWM's sales of 35N LT wire and on the fact that 35N LT wire has largely displaced other available biocompatible alloys for use in several surgical implant applications. I also base this conclusion on direct feedback from customers for 35N LT wire for use in certain surgical implant applications – those customers state that they chose FWM's 35N LT wire over wire formed from other available alloys because of the FWM product's superior fatigue resistance.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Date: 9/7/2007


Robert J. Myers

35N LT
of Part Numbers per Year

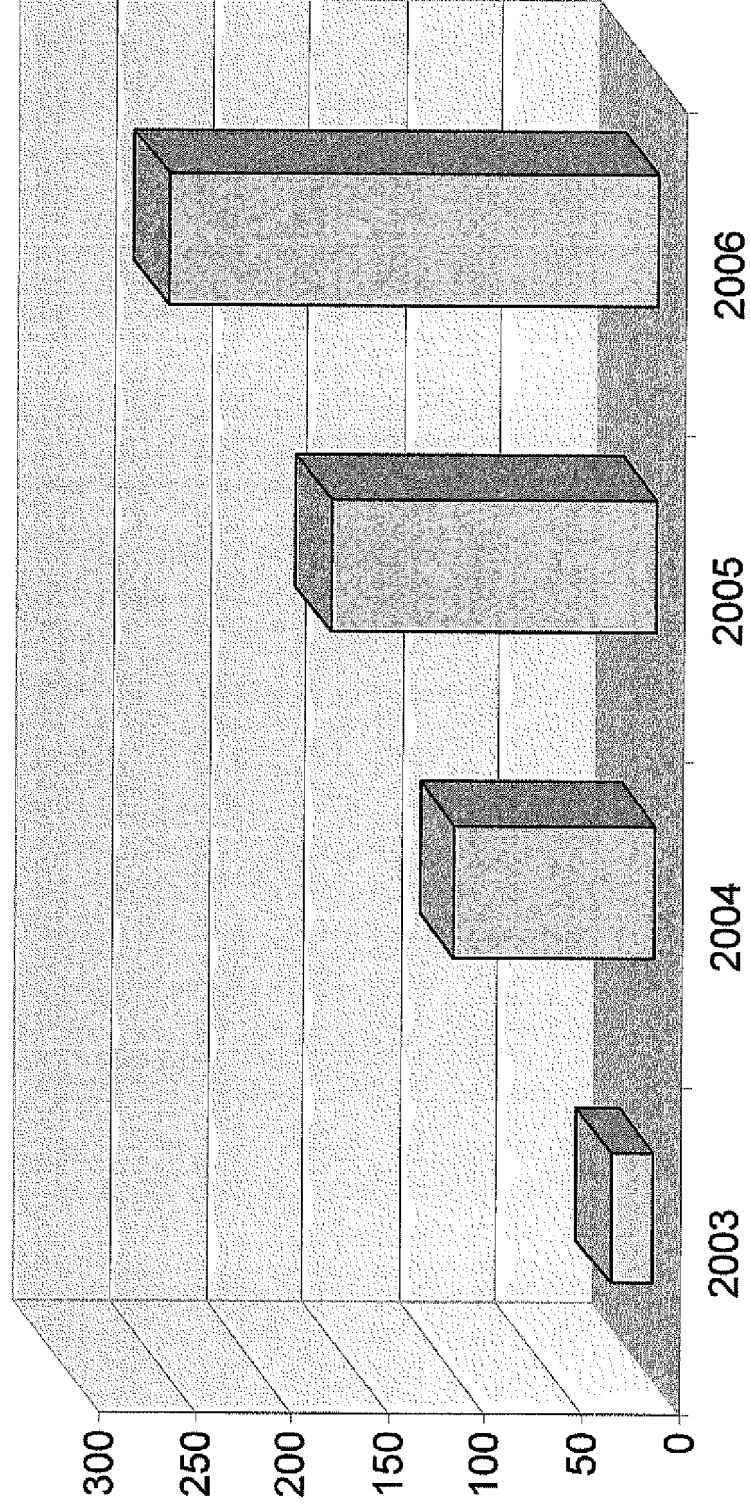


FIGURE 1

35N LT
Total Feet per Year

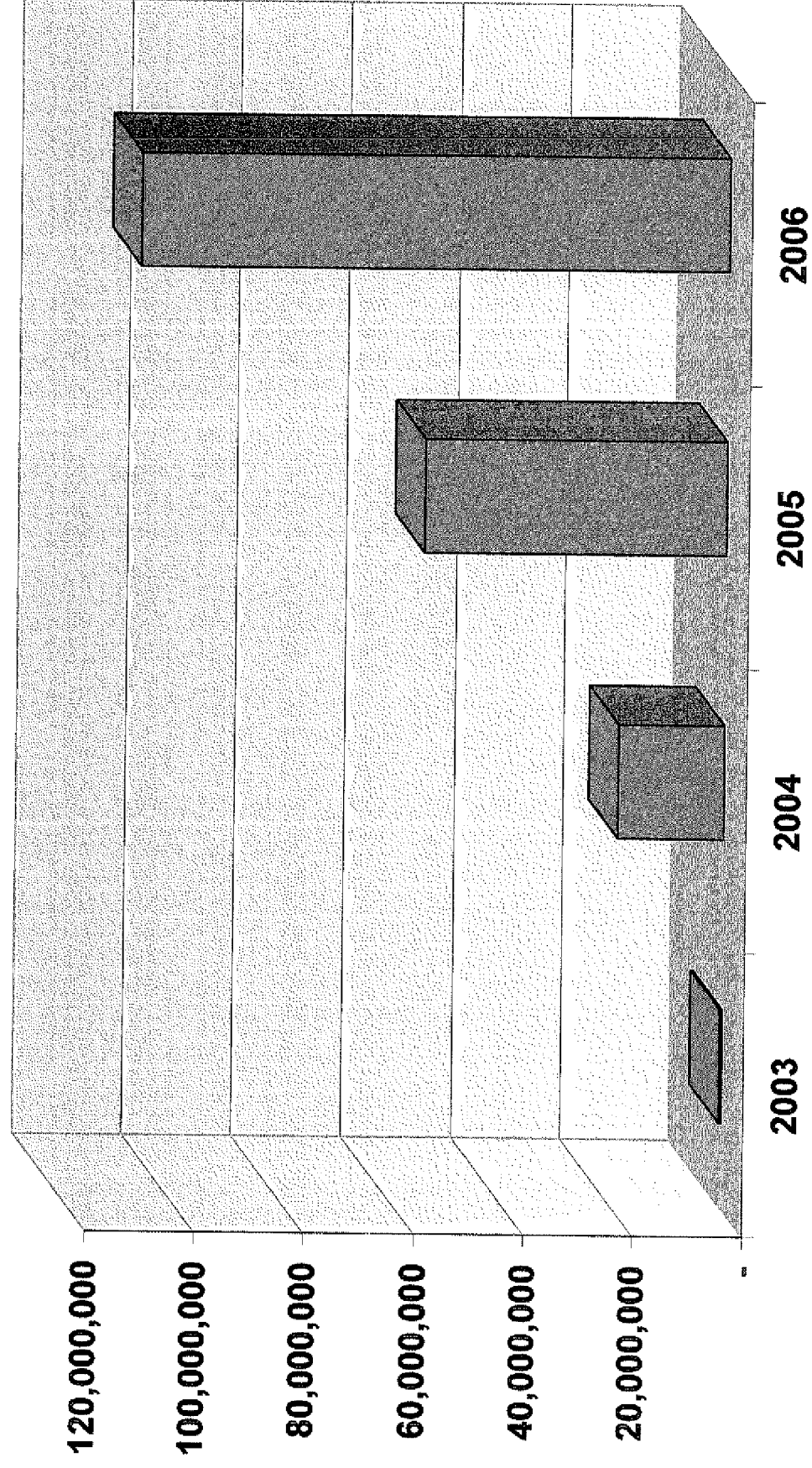


FIGURE 2